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DEPARTMENT OF HEALTH AND HUMAN SERVICES National Institutes of Health

Proposed National Toxicology Program (NTP) Review Process for the Report on Carcinogens: Request for Public Comment and Listening Session

AGENCY: Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH).

ACTION: Request for Public Comment and Announcement of Listening Session

SUMMARY: The NTP invites written public comment on the proposed Report on Carcinogens (RoC) review process and announces a public listening session to receive oral comments on the proposed process.

DATES: The deadline for submission of written comments is November 30, 2011, and the deadline to register for the public listening session is November 21, 2011. The public listening session will be held November 29, 2011, 1-5 PM (EST), although it may end earlier depending on the number of registered speakers and will be cancelled if there are no registrants by the close of business (COB) on November 21, 2011. Registrants will receive information to access the listening session on or before November 22, 2011, and speakers should send talking points or slides by COB on November 21, 2011.

ADDRESSES: Written comments should be sent to Dr. Ruth Lunn, Director, Office of the Report on Carcinogens, DNTP, NIEHS, P.O. Box 12233, MD K2-14, Research Triangle Park, NC 27709; *telephone:* (919) 316-4637 or email *lunn@niehs.nih.gov*. Courier address: NIEHS, Room 2006, 530 Davis Drive, Morrisville, NC 27560. Registration for the listening session is via the NTP website (*http://ntp.niehs.nih.gov/go/rocprocess*). TTY users should contact the

Federal TTY Relay Service at 800-877-8330. Requests must be made at least 5 business days in advance of the listening session.

FOR FURTHER INFORMATION CONTACT: Questions or comments should be directed to Dr. Lunn (see "ADDRESSES").

SUPPLEMENTARY INFORMATION:

Background Information on the RoC and its Review Process

The RoC is a science-based, public health document, required by Congress to be published every two years (Public Health Services Act sec. 301(b)(4), 42 U.S.C. 241(b)(4)). The RoC provides information on substances that may pose a hazard to human health by virtue of their carcinogenicity (for more information see http://ntp.niehs.nih.gov/go/roc). Substances are listed in the report as either https://ntp.niehs.nih.gov/go/roc). The NTP prepares the RoC on behalf of the Secretary of Health and Human Services. The 12th RoC was published in June 2011.

The NTP followed an established process for the review of substances for the 12th RoC. The NTP is proposing changes to the review process for listing substances in the 13th RoC to enhance transparency and efficiency and to enable the NTP to publish the RoC in a timelier manner. The NTP also seeks to maintain critical elements of the existing process including external scientific and public involvement, scientific rigor, and external peer review. The proposed RoC review process is available on the NTP RoC website (http://ntp.niehs.nih.gov/go/rocprocess).

Request for Public Comment

The NTP invites written and oral comments on the proposed RoC review process.

Written comments should be sent to Dr. Ruth Lunn (see "ADDRESSES") by November 30,

2011. Individuals submitting written public comments are asked to include relevant contact information (name, affiliation and sponsoring organization (if any), telephone, and email).

Written submissions will be posted on the RoC website as they are received and the submitter will be identified by name, affiliation, and/or sponsoring organization.

The NTP will hold a listening session using Adobe® Connect™ on November 29, 2011, from 1-5 PM (EST) to receive oral comments on the proposed RoC review process. The listening session may end earlier depending on the number of registered speakers and will be cancelled if there are no registrants by COB on November 21, 2011. If the event is cancelled, notification will be posted on the RoC website (http://ntp.niehs.nih.gov/go/rocprocess). Individuals who wish to participate in the listening session as either speakers or observers must register by November 21, 2011, at http://ntp.niehs.nih.gov/go/rocprocess. There will be 50 connections available for registrants including speakers plus observers. Registration to present oral remarks is limited to the first 15 registrants who wish to speak with one time slot per organization. The NTP will send registrants instructions to access the listening session on or before November 22, 2011. A maximum of 15 minutes will be allotted per speaker. Registered speakers should submit their oral statement and/or slides to Dr. Lunn by COB on November 21, 2011. All statements and/or slides will be posted on the RoC website with the speaker identified by name, affiliation, and/or sponsoring organization.

The NTP will carefully review both the written and oral comments received on the proposed

RoC review process and consider what changes, if any, might be needed. The NTP plans to post

the finalized RoC review process on the RoC website (http://ntp.niehs.nih.gov/go/rocprocess)

and present it at the next NTP Board of Scientific Counselors meeting on December 15, 2011.

Details about this meeting will be published in the Federal Register and posted on the NTP

website at http://ntp.niehs.nih.gov/go/165.

Dated: October 24, 2011

John R. Bucher,

Associate Director, National Toxicology Program

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